Patient experience of pain during vaginal pessary removal and insertion: a service evaluation study.

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Authors' contributions to the manuscript

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Abstract

Introduction: Pelvic organ prolapse is a common problem affecting women, but there is currently a lack of research focusing on patient experience of pessary changes. This study aimed to capture the patient perspective of pessary changes and to formally assess pain during pessary removal and insertion.

Methods: A service evaluation request was granted by South Tees Hospitals NHS Trust. Patients undergoing pessary change (ring, shelf, or Gellhorn) in gynaecology outpatient clinics over a six-month period were asked to rate their pain scores on a 10 point numerical-pain-rating-scale. Other associated data was collected.

Results: Out of 213 women, 58.2% reported that pessary removal was more painful than insertion, 30.5% reported equal pain, and 10.8% reported insertion was more painful than removal. Pain scores were significantly higher for removal 4.37 (4, 4-7) than for insertion 2.66 (2, 2-4) [mean (median, IQR), p <.001]. Ring pessaries were significantly less painful to both remove and insert than shelf and Gellhorn pessaries. Smaller pessaries were more painful to both remove and insert. There was no significant difference in pain scores reported by those with or without diagnosed vulval conditions.

Conclusions: Pessary removal causes most women moderate pain, which should be communicated to patients beforehand. Ring pessaries are significantly less painful to change compared to other pessary types. Clinicians should consider pain as a factor in their decision-making surrounding pessary choice and when counselling patients. Future research should focus on ways to reduce pain during pessary removal.

Keywords: Patient experience, Pain, Pelvic-organ prolapse, Pessary changes, Vaginal pessaries

Brief summary: This service evaluation explores patient experience of pessary changes. Removal is more painful than insertion. Ring pessaries are less painful to change than other pessaries.

Abbreviations:

- **HRT** – hormone replacement therapy
- **NRS** – numerical rating scale
- **POP** – pelvic organ prolapse

Introduction

Pelvic organ prolapse (POP) is a common problem affecting women, with up to 40% of all women and up to 60% of parous women experiencing a degree of POP in their lifetime [1-3]. Commonly described symptoms of POP include a “dragging down” sensation in the vagina, vaginal lump or bulge, changes in urinary or bowel habit, and discomfort or difficulty during sexual intercourse [3]. Treatment options for POP include conservative management, lifestyle changes, pelvic floor muscle exercises, local oestrogen therapy, vaginal pessaries, and surgical management. Lifetime risk of prolapse surgery by the age of 80 in the UK is estimated to be 9.5% [4]. A recent Cochrane review reports that 77% of gynaecologists choose pessaries as the first-line management of POP [1, 5].

Vaginal pessaries are mechanical devices that act to support the vagina and restore prolapsed organs to their correct anatomical position. There are many different types of vaginal pessaries, including ring, shelf, and Gellhorn pessaries [5]. The choice of pessary depends on patient anatomy, the patient’s desire to continue with penetrative vaginal intercourse, and clinician preference. There is a perception among clinicians that pessary removal is simpler than (re-)insertion and most clinicians will start with a ring pessary as they are considered the easiest to insert [5-7]. If a ring pessary is ineffective and the patient is not sexually active, Gellhorn and shelf pessaries can be considered.

UK guidelines recommend pessary change (removal followed by re-insertion of the washed pessary or insertion of a new one) at least once every six months [8]. Side effects of pessary use include vaginal abrasion and/or ulceration, new or worsening stress urinary incontinence, difficulty with bowel evacuation, bacterial colonisation resulting in offensive discharge, and rarely, fistula, and vaginal cancer [1, 9, 10]. Some women report significant pain and/or experience skin breaks during pessary changes, anecdotally noted more frequently in women with perineal skin disease, such as lichen sclerosus. One recent clinical audit concluded that women who self-manage vaginal ring pessaries with monthly changes had significantly lower rates of adverse side effects described above [11]. However, that audit failed to address acute pain experienced during the more frequent pessary changes. Furthermore, there is a lack of consensus on the effect of pain and analgesic options for pessary changes themselves [9-16].

Previously published studies relating to pessary use have explored the frequency of side effects, complications of long-term use [10, 13-16], and clinician perspective of pessary placement [6].

However, there is a need for more studies focusing on patient experience of pessary changes. This study aimed to capture the patient perspective of pessary changes and formally assess pain as a factor in this experience.

Materials and Methods

This service evaluation study included patients who underwent a pessary change in gynaecology outpatient clinics in a large university teaching hospital between April 2022 and December 2022. The clinics included those led by consultants, nurses, and specialist nurses. Patients were verbally consented and asked to report the level of pain felt on a validated zero-to-ten numerical rating scale (NRS) for both removal and subsequent (re-)insertion of a pessary. The NRS is valid and reliable across different cultures and languages. Pain scores on the NRS correlate with the intensity of pain experienced: 0 indicates no pain, 1-3 indicates mild pain, 4-6 indicates moderate pain, and 7-10 indicate severe pain [17, 18]. A paper questionnaire was provided for patients to complete at the end of their pessary clinic appointment, aiming to capture their immediate reflections on their experience of pain during pessary change. We collected data on use of vaginal HRT, diagnosed vulval skin conditions, duration of pessary use, if this was their first pessary change, size of pessaries inserted and removed, and any perineal trauma sustained during pessary removal. Missing data were excluded from the analysis.

Jamovi 2.3 was used for all statistical analysis. Wilcoxon paired non-parametric testing compared pain scores for pessary removal and insertion. Mixed factorial *ANOVA* testing compared the differences in pain scores for removal and insertion by the three pessary subgroups (ring, shelf, and Gellhorn). Backward regression analysis was used to study the relationships between pain (on removal and then on (re-)insertion) and the following factors: patient age, pessary size, pessary type, use of vaginal HRT, diagnosed vulval/ vaginal condition (lichen sclerosus, genital atrophy, vaginal erosion), perineal trauma, and whether it was the first pessary change or not.

This project was approved locally as a service evaluation and therefore ethics approval was not required. Neither patients nor the public were involved in the study design.

Results

A total of 213 patients were included in this study (Table 1). Mean age of patients was 76 years, ranging from 46 to 92 years old. The mean duration of pessary use was 4.4 years. Overall, 58.2% of women reported that pessary removal was more painful than insertion, 30.5% reported that removal and insertion were equally painful, and 10.8% reported that insertion was more painful than removal.

Median removal pain was classed as "moderate" and was significantly greater than median insertion pain, which was "mild" (4 [IQR:4-7] vs 2 [IQR:2-4], $p<.001$). This pattern of increased pain on removal compared to insertion remains the same across ring, shelf, and Gellhorn pessaries ($p = 0.08$), as shown in Figure 1b. There is a significant interaction with perineal trauma and pain, with trauma sustained during pessary removal being associated with higher pain scores ($p<.001$), but no subsequent difference during insertion, as shown in Figure 1c.

Further results of statistical analyses are detailed in Tables 2 (removal) and 3 (insertion). Ring pessaries are significantly less painful to both remove ($p<0.01$) and insert ($p<0.05$) than shelf and Gellhorn pessaries. Ring pessary removal and insertion caused mild pain, whilst shelf and Gellhorn pessaries caused moderate pain. Although both shelf and Gellhorn pessary changes are associated with worse pain than ring pessaries, there is no statistically significant difference between removal and insertion of shelf compared to Gellhorn pessaries.

Smaller pessaries were associated with more pain on both removal ($p<0.05$) and insertion ($p<0.05$). Results demonstrated no significant relationship between the use of vaginal HRT and pain of pessary removal or insertion.

The apparent predictor of age and increased pain is due to artefact as age is strongly associated with the type of pessary chosen, rendering the effect of age on pain non-significant. Shelf pessaries are associated with increased pain on both removal ($p<0.01$) and insertion ($p<0.05$) than ring pessaries and these patients tend to be older (see Figure 2).

Discussion

The first key finding from this study is that many patients find ring, shelf, and Gellhorn pessary removal "moderately painful" according to the numerical pain ranking scale [17, 18] with a mean pain score of 4.4 for pessary removal (all subgroups). Although the pain experienced during pessary changes appears to be short-lived, our results demonstrate that it remains significant from a patient perspective. It is important that patients are made aware of the likelihood of moderate pain, as opposed to “mild discomfort” during pessary changes.

The second key finding is that pessary removal is significantly more painful than insertion. Despite anecdotal evidence that removal is easier than insertion from a clinician perspective [7], it is vital that clinicians consider the patient perspective and inform patients that pessary removal will likely be more painful.

The third key finding is that ring pessaries are significantly less painful to both remove and insert than shelf and Gellhorn pessaries. As these are three of the most used pessary types, clinicians should consider ring pessaries as the first-line option, when appropriate, to improve the patient experience of changes. Anecdotal evidence indicates that smaller ring pessaries are considered by clinicians to be more uncomfortable to insert [7]. This is clearly reflected in our patient population as our study shows a significant inverse relationship between pessary size and pain during removal and insertion. This can be explained by the inability to reduce the diameter of the pessary before removing it, whilst this is usually possible by digital compression before insertion, especially for ring pessaries. Another explanation is that a smaller pessary is usually used in a patient with a smaller introitus and a smaller introitus may be less stretchable compared to a large introitus. Given these results, clinicians should not refrain from using bigger pessary sizes to trouble-shoot fitting issues due to concerns that they might cause more pain, assuming they are not limited by patient anatomical factors including short vaginal length and/or small genital hiatus measurements”.

Patients using vaginal HRT reported lower pain scores, however this relationship was not statistically significant. This may be due to the limited number of patients (n=49) using vaginal HRT in this analysis.

A limitation of this study was the small number of patients (n=10) with diagnosed vulval skin conditions. Although our results demonstrate that pessary removal and insertion are 1.9 and 2.7 times more painful, respectively, in the presence of vulval skin disease, the small patient numbers make it difficult to draw convincing conclusions from these results. A further limitation was the small number of patients using shelf pessaries, therefore our findings may not be robustly applicable to those patients. We did not collect data on chronic pain conditions and use of painkillers, which could potentially affect the level of pain experienced. This study was also limited by some patients not responding to all questions on the questionnaire proforma, resulting in data exclusion and possible selection bias. Unfortunately, our questionnaire did not collect data on who was performing the pessary change, be it consultant, nurse specialist, or nurse. This would be interesting to analyse in a future study. Patients completed the paper questionnaires at the end of their clinic appointments, which could have resulted in a degree of response bias if patients under- or over-reported symptoms due to awareness that the present clinician could view their non-blinded responses. It is also possible that there is some interaction with another variable that we have not identified.

Despite the limitations of our study, our results clearly demonstrate that pessary removal causes most women moderate pain and that ring pessaries are significantly less painful to remove and insert than shelf and Gellhorn pessaries. These findings should be clearly communicated to all patients considering pessary treatment, undergoing routine pessary changes, and considering changing from use of a ring pessary to a shelf or Gellhorn. Clinicians should consider pain as a factor in their decision-making surrounding pessary choice and when counselling patients for self-management of pessaries.

Future related research should focus on methods of improving patient experience of pessary changes, including further consideration of analgesic options including the effect of pre-procedure oral analgesia, inhaled nitrous oxide, or local anaesthetic (e.g., lidocaine) use. There is a need for further larger-scale studies to establish the relationship between genitourinary syndrome of menopause and associated vaginal oestrogen use with pain during pessary changes. There is scope for research surrounding the impact of genital hiatus measurements and use of tenaculum and sponge forceps during pessary changes. It is also important that manufacturers consider pessary designs which have the potential to limit pain experienced by patients during pessary changes.

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Figure Legends

Figure 1: (a) Mean pain scores (0-10) for pessary removal and insertion, inclusive of all pessary subtypes (ring, shelf, and Gellhorn); (b) Mean pain scores (0-10) for individual pessary subtype (ring, shelf, or Gellhorn) removal and insertion; (c) Mean pain scores (0-10) for pessary removal and insertion with/without trauma sustained during removal.

Figure 2: Mean ages of patients using ring, shelf, and Gellhorn pessaries.

Tables

Table 1: Demographics of pessary use

Demographics	Mean (years)	Range (years)
Age at clinic visit	76	46 – 92
Duration of pessary use	4.4	0.5 – 20
Type of pessary used	Number of patients	Percentage of total patients
Ring pessary removed	110	51.6%
Ring pessary inserted	113	53.1%
Shelf pessary removed	18	8.45%
Shelf pessary inserted	18	8.45%
Gellhorn pessary removed	80	37.6%
Gellhorn pessary inserted	78	36.6%
No pessary to remove	5	2.35%
Pessary not inserted after removal	4	1.88%
Report of removal/insertion pain	Number of patients	Percentage of total patients
Removal more painful than insertion	124	58.2%
Equally painful	65	30.5%
Insertion more painful than removal	23	10.8%

Table 2: Pain on pessary removal (final model)

Model coefficients – pain on removal				
			95% Confidence Interval	
Predictor	***p***	**Odds ratio**	**Lower**	**Upper**
Size removed	**0.029**	**0.969**	0.943	0.997
Trauma on removal (yes – no)	**0.003**	**3.197**	1.488	6.920
Pessary type removed:				
Shelf – Ring	**0.007**	**3.212**	1.379	7.558
Gellhorn – Ring	**0.007**	**2.054**	1.216	3.486
Shelf – Gellhorn	0.312	1.564	0.656	3.744

Table 3: Pain on pessary insertion (final model)

Model coefficients – pain on removal				
			95% Confidence Interval	
Predictor	***p***	**Odds ratio**	**Lower**	**Upper**
Size inserted	**0.041**	**0.972**	0.945	0.999
Pessary type inserted:				
Shelf – Ring	**0.031**	**2.563**	1.091	6.078
Gellhorn – Ring	**>0.001**	**4.344**	2.527	7.562
Shelf – Gellhorn	0.244	0.590	0.242	1.437

Appendix 1 – Proforma Questionnaire

1. Are you using any vaginal HRT: No / Oestrogen cream / Vagifem (please circle)

2. If yes, how often: Once a week / Twice a week / Other .... (please circle or write)

3. Have you been diagnosed with a specific vulval skin condition: No / Lichen sclerosus / Other ....

4a. Is this your first pessary change: Yes / No

4b. How long have you used pessaries for? .... years

5. How painful did you find the removal of your ring / shelf / Gellhorn pessary (on a 0-10 scale) ....
0 = no pain, 10 = worse pain, like labour pain

6. Size of the removed pessary ....

7. Trauma to the perineum: No / Yes, estimated size of tear .... mm

8. How painful did you find the (re-)insertion of your pessary (on a 0-10 scale) ....
0 = no pain, 10 = worse pain, like labour pain

9. Size of the newly inserted ring / shelf / Gellhorn pessary ....